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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,672	06/14/2005	Peter Gerardus Franciscus Cox	I-2002.024 US	4775

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PATENT DEPARTMENT
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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
11/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,672	COX ET AL.	
	Examiner	Art Unit	
	Samira Jean-Louis	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Sheet (1)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-12 are currently pending in the application.

Applicant's election of Group I (i.e. pharmaceutical composition) in the reply filed on 10/24/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d) for foreign priority based on an application filed in Europe on 05/30/2002, which papers have been placed of record in the file of PCT/EP03/50192.

Objections

The abstract of the disclosure is objected to because it contains legal phraseology such as "comprising" on line 2. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, and 7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Farnsworth et al. (Canadian J. of Comp. Med. July 1975, Vol. 39, Iss. 3, pp. 340-348, already cited by applicant and filed with an IDS 1449) in view of Lohuis et al. (J. Dairy Sci., 1989, Vol. 72, pp. 75-98, already cited by applicant and filed with an IDS 1449).

Farnsworth et al. teaches a composition comprising an antibiotic (i.e. antibacterial agent) and steroid treatment in cows (see abstract and Materials and Methods section, pp. 341, paragraph 1, line 1). In particular, Farnsworth discusses the

use of sterile water (i.e. carrier) as the diluent for 250 mg dihydrostreptomycin (i.e. antibacterial agent vs. instant claim 7) and 10 mg of prednisolone (see Materials and Methods section, pp. 342, paragraph 6, lines 1-8) injected into the teat cistern (i.e. mammary glands) of cows (Materials and Methods section, pp. 342, paragraph 6, lines 14-15).

Farnsworth et al. does not specifically teach a composition comprising at least 20 mg of prednisolone per unit dose.

However, Lohuis et al. teaches the use of 40 mg of prednisolone as an intramammary infusion in lactating cows (see abstract and animal section of Materials and Methods, pp. 241).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to discover the optimum or workable ranges of prednisolone through routine experimentation as evidenced by Lohuis to arrive at a therapeutically effective composition since Farnsworth et al. teaches a composition of prednisolone and antibiotics in an aqueous solution. Given that Farnsworth teaches a prednisolone and antibiotics composition, one of ordinary skill would have been motivated to modify the composition of Farnsworth et al. with the expectation of providing a composition that is therapeutically effective comparable to applicant's invention.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farnsworth et al. (Canadian J. of Comp. Med. July 1975, Vol. 39, Iss. 3, pp. 340-348, already cited by applicant and filed with an IDS 1449) in view of Lohuis et al. (J. Dairy Sci., 1989, Vol. 72, pp. 75-98, already cited by applicant and filed with an IDS 1449) as applicable to claims 1-3, and 7 above and in further view of Hornish et al. (Current Topics in Med. Chem. July, 2002, Vol. 2, Iss. 7, pp. 717-731, already cited by applicant and filed with an IDS 1449).

The Farnsworth and Lohuis references are as discussed above and incorporated by reference herein. However, Farnsworth and Lohuis do not address the use of specific cephalosporins as the antibacterial agents in the aforementioned composition.

Hornish et al. teaches the use of cephalosporins for treatment of mastitis infections and/or respiratory disease in cattle (see abstract). Hornish further teaches the use of first generation cephalosporins such as cephapirin against gram positive pathogenic cocci (see table 2 and pp. 719, paragraph 1) or the use of fourth generation cephalosporins such as cefquinome with greater potency to a broader range of organisms and enhanced transportability across the blood-membrane barrier (see table 2 and pp. 719, paragraph 4).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to combine the composition of Farnsworth and Lohuis in view of the

knowledge of cephalosporins as potent antibacterial agents provided by Hornish. Given that Farnsworth teaches a composition of prednisolone and antibacterial agent and Lohuis discloses an effective dosage of prednisolone, and Hornish discloses the use of cephalosporins as potent antibacterial agents, one of ordinary skill would have been motivated to combine the composition of Farnsworth et al. and Lohuis et al. with the disclosure of Hornish et al. with the expectation of providing a potent composition that is therapeutically effective.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

11/05/2007